Paper No. 19

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte SHALOM Z. HIRSCHMAN

Appeal No. 2004-1212
Application No. 09/316,624

ON BRIEF

Before SCHEINER, GRIMES, and GREEN, Administrative Patent Judges.

GRIMES, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 1-4, all of the claims remaining. Claim 1 is representative and reads as follows:

1. A method of ameliorating a symptom of rheumatoid arthritis in a patient suffering from rheumatoid arthritis, comprising parenterally administering to said patient an effective symptom ameliorating amount of Product R in a range from about 2.5 microliters to about 40 microliters per kilogram of body weight per day in a pharmaceutically acceptable formulation.

The examiner relies on the following reference:

Kochel	5,849,196	Dec. 15, 1998

Appellant relies on the following reference:

Friedland et al. (Friedland)	6,303,153	Oct. 16, 2001

Claims 1-4 stand rejected under 35 U.S.C. § 112, second paragraph, as indefinite.

Claims 1-4 also stand rejected under 35 U.S.C. § 102(e) as anticipated by Kochel.

We reverse both rejections.

Background

"RETICULOSE® emerged as an antiviral product in the 1930's. . . . Product R is a refinement of RETICULOSE® prepared by an improved manufacturing process. It is a peptide nucleic acid preparation with defined composition." Specification, page 7. The specification defines Product R as the product of either of two specific methods. See pages 10-12.

The specification discloses that Product R is an effective treatment for autoimmune diseases, including rheumatoid arthritis. See pages 1, 2, and 12. The specification describes a working example in which "[a] clinical trial to assess the efficacy of Product R in patients suffering from rheumatoid arthritis (RA) has been conducted." Page 14. Treatment with Product R was reported to result in decreased pain, swelling, inflammation, and morning stiffness, and improved joint mobility and ability to carry out various activities. See pages 15-18.

Discussion

Claim 1, the broadest claim on appeal, is directed to a method for ameliorating a symptom of rheumatoid arthritis comprising parenterally administering "an effective symptom ameliorating amount of Product R in a range from about 2.5 microliters to about 40 microliters per kilogram of body weight per day." The examiner rejected the claims as indefinite and anticipated.

1. Definiteness

The examiner rejected the claims under 35 U.S.C. § 112, second paragraph, on the basis that "[t]he metes and bounds of the phrase 'effective symptom ameliorating amount' in claims 1 and 4 are unclear." Examiner's Answer, page 3.

Appellant argues that "[t]here is nothing unclear about the claim language 'an effective symptom ameliorating amount of Product R in a range from about 2.5 microliters to about 40 microliters per kilogram of body weight per day'[;] . . . Product R is a substance in liquid form made according to a specific process described in the application." Appeal Brief, page 9.

We agree with Appellant that the claims mean what they say: an "effective symptom ameliorating amount" of Product R is a daily dosage of 2.5 to 40 µl per kilogram of the patient's body weight. The specification defines Product R as the product resulting from one of two described procedures, and the claims require administration of defined quantities of that (liquid) product. The claim language that the examiner objected to – "effective symptom ameliorating amount" – is essentially duplicative of the quantities expressly recited in the

claim. Cf. Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc., 246 F.3d 1368, 1375, 58 USPQ2d 1508, 1513 (Fed. Cir. 2001) ("[T]he expression 'an antineoplastically effective amount' . . . [is an] expression of intended result [that] essentially duplicates the dosage amounts recited in the claims. . . . The express dosage amounts are material claim limitations; the statement of the intended result of administering those amounts does not change those amounts or otherwise limit the claim.").

2. Anticipation

The examiner also rejected claims 1-4 as anticipated by Kochel, reasoning that Kochel discloses that a composition of low molecular weight peptides (8-15 kD), derived from Reticulose® by filtration, is useful in treating rheumatoid arthritis. See the Examiner's Answer, page 4. The examiner concluded that

> Kochel sets forth products derived from the known product Reticulose® and methods of using that product, as claimed. The methods Kochel used to produce the composition, as well as the methods of treating rheumatoid arthritis, are very similar to those of the claimed invention. Whether the products resulting from the process are the same, is not clear, and the Office does not have the facilities to perform such comprehensive analyses.

Id., page 5.

Appellant argues that the record shows that Product R is different from Reticulose®. Specifically, Appellant cites Friedland, a commonly assigned U.S. Patent, which compares the properties of Product R and Reticulose®. (Friedland's method of making Product R is the same as that disclosed on pages 10-11 of the instant specification.)

Among other things, Friedland discloses that the components of Product R and Reticulose® have different molecular weight distributions, as well as different ratios of UV absorbancies. See Table IV (column 10). Friedland also reports that, although Kochel characterized the low molecular weight fraction of Reticulose® as inhibiting phagocytosis by neutrophils (see Kochel, column 2, lines 46-55), Product R does not have similar activity. See Table IV. Finally, Friedland compares the starting materials for ten-liter batches of Reticulose® and Product R (Table V) and concludes that "the initial protein concentration for the RETICULOSE® preparation is twice as much as that for the Product R preparation." Column 10, lines 44-46.

We agree with Appellant that the evidence of record shows that the Product R recited in the instant claims is different from the Reticulose® preparation disclosed by Kochel. We therefore reverse the rejection under 35 U.S.C. § 102(e).

We note in closing that the examiner may have intended the rejection to be based more on obviousness than anticipation: Kochel does not isolate any low molecular weight fractions of Reticulose®, or describe how to do so, but the section of Kochel cited by the examiner as teaching treatment of rheumatoid arthritis states that a low molecular weight fraction of Reticulose® is "effective in treating auto immune diseases." Column 3, lines 1-11. If the examiner is of the view that Kochel would have made obvious the instantly claimed method, even though it does not anticipate, a rejection under 35 U.S.C. § 103 may be appropriate.

Before entering such a rejection, however, the examiner should consider whether those of skill in the art would have been motivated to practice the instantly claimed method; whether they would had a reasonable expectation of success; whether the prior art was enabling for the low molecular weight fraction discussed by Kochel; and whether the evidence is sufficient to show that such a low molecular weight fraction would have been the same as the Product R described in the instant specification. In respect of the latter consideration, the examiner should note that the Friedland patent claims Product R as a composition; the apparent novelty and nonobviousness of Product R are factors that should be considered in any future prosecution. Cf. In re Ochiai, 71 F.3d 1565, 1569, 37 USPQ2d 1127, 1131 (Fed. Cir. 1995): "The process invention Ochiai recites in claim 6 specifically requires use of none other than its new, nonobvious acid as one of the starting materials. One having no knowledge of this acid could hardly find it obvious to make any cephem using this acid as an acylating agent, much less the particular cephem recited in claim 6."

Summary

The examiner has not adequately shown that those skilled in the art would have considered the claims indefinite, or that the claimed method was identically disclosed in the prior art. The rejections under 35 U.S.C. §§ 102(e) and 112, second paragraph, are reversed.

REVERSED

Toni R. Scheiner)
Administrative Patent Judge)
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Eric Grimes) BOARD OF PATENT
Administrative Patent Judge)
) APPEALS AND
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Lora M. Green)
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